



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT 16

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference MJL/C403.02/U		FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB99/01902	International filing date (day/month/year) 15/06/1999	Priority date (day/month/year) 15/06/1998	
International Patent Classification (IPC) or national classification and IPC C12N15/54			
Applicant NATIONAL STARCH AND CHEMICAL INVESTMENT HOLDING CO			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 8 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none">I <input checked="" type="checkbox"/> Basis of the reportII <input checked="" type="checkbox"/> PriorityIII <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicabilityIV <input type="checkbox"/> Lack of unity of inventionV <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statementVI <input type="checkbox"/> Certain documents citedVII <input checked="" type="checkbox"/> Certain defects in the international applicationVIII <input checked="" type="checkbox"/> Certain observations on the international application			
Date of submission of the demand 27/12/1999		Date of completion of this report 23.08.2000	
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**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB99/01902

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-28 as originally filed

Claims, No.:

1-29 as originally filed

Drawings, sheets:

1/13-13/13 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

II. Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:
- ☐ copy of the earlier application whose priority has been claimed.
- ☐ translation of the earlier application whose priority has been claimed.
2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid.

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Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

see separate sheet

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	10, 12-15, 18-25, 29
	No:	Claims	1-9, 11, 16-17, 26-28
Inventive step (IS)	Yes:	Claims	-
	No:	Claims	1-29
Industrial applicability (IA)	Yes:	Claims	1-29
	No:	Claims	-

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB99/01902

Re Item I

Basis of the report

The examination is being carried out on the following application documents:

Text for the Contracting States:

AT BE CH DE DK ES FI FR GB GR IT IE LI LU MC NL PT SE

Description, pages:

1-28 as originally filed

Claims, No.:

1-29 as originally filed

Drawings, sheets:

1/13-13/13 as originally filed

Re Item II

Priority

Priority was found to be invalid for claims 16 and 17. Both claims are based on Example III of the description. This example, however, was not part of the priority document. The priority document only discloses an increase of short chains (DP 6&7) and a depletion of long chains (DP 15-20). Therefore document D 5 is relevant for assessing novelty and inventive step of these claims.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: DE 44 41 408 A (INST GENBIOLOGISCHE FORSCHUNG) 15 May 1996 (1996-05-15)

D2: WO 97 20040 A (AMYLOGENE HB ;EK BO (SE); KHOSNOODI JAMSHID (SE);

LARSSON CLAS TOM) 5 June 1997 (1997-06-05)

D3: EP-A-0 779 363 (NAT STARCH CHEM INVEST) 18 June 1997 (1997-06-18) cited in the application

D4: WO 97 22703 A (DU PONT ;HUBBARD NATALIE LOUISE (US); KLEIN THEODORE MITCHELL (US)) 26 June 1997 (1997-06-26)

D5: EDWARDS, ANNE ET AL: 'A combined reduction in activity of starch synthases II and III of potato has novel effects on the starch of tubers' PLANT J. (1999), 17(3), 251-261

1. Novelty (Article 33(2) PCT):

Claims 1-9, 11, 16-17, 26-28 are not novel for the following reasons:

1.1 Document D1 discloses all features of present claims 1-9. Of particular relevance are pages 5-7, where the following is disclosed:

- a method of modification by introduction of a combination of sequences
- wherein the sequences code for starch synthase or are functionally equivalent
- wherein each sequence is operably linked to a promoter (see p. 6, l. 59ff)
- simultaneous introduction of two sequences, in this case on the same vector
- modification of at least one starch property (p. 6, l. 32 and p. 7)
- antisense expression (p. 5, l. 33 and p. 7, l. 6 ff)
- introduction of the vector into a plant (Example 5, potato)

1.2 The method of present claim 4 is anticipated by D1 for the same reasons as outlined above. Claim 4 comprises the following method steps:

- introduction of a first sequence encoding starch synthase into plants
- selection of the plants obtained

The introduction of a second sequence is merely proposed ("...selected for introduction of...") and therefore does not represent a further step of the method. Even if this was the case the claim would not be inventive, as stepwise introduction of different genes is known in the art.

As the applicant correctly stated in his letter of reply, claim 4 is dependent on claim 1. However, as claim 4 relates to the introduction of only one sequence whereas claim 1 relates to the introduction of a combination of sequences, this

dependency is contradictory in itself.

- 1.3 Claim 11 is a product by process claim. Such claims, defined in terms of a process of manufacture (in this case production by a plant) before the EPO are only admissible if the products as such fulfil the requirements for patentability (i.e. they have to be novel and inventive).

In the present case starch is generally known, and also examples for starch with altered specificities exist (see D2). Furthermore, the starch of claim 11 cannot be distinguished from any identical starch produced by any other method (i.e. chemically altered starch). Claim 11 therefore is not novel.

Concerning product-by-process claims, the same argumentation applies to claims 12-15, 18-23, and 29 (see 2.3).

- 1.4 As already outlined in section II, parts of the subject-matter of claims 16 and 17 did not form part of the priority document. The priority document discloses an increased amount of starch with a degree of polymerisation 6&7, and a depletion in the region 15-20. The ranges 8-10 and 21-24 are therefore not covered by the priority and are anticipated by document D5 which discloses (p. 258) the ranges 7-13 and greater than 15.

In addition, document D4 discloses starch with a depletion of molecules having a chain length in the range of 15-24 (see tables 3, 6, and 8). Thus claim 17 is not novel.

- 1.5 Claims 26 to 28 are not novel for the same reasoning as given in 1.1.

2. Inventive step (Article 33(3) PCT):

The argumentation concerning inventive step is based on documents published before the priority date of the present application.

Claims 10, 12-15, 18-25, and 29 are considered not to be inventive for the following reasons:

- 2.1 Documents D1 and D2 both deal with the production of starch exhibiting altered properties. Whereas D2 makes use of a single gene construct, i.e. the starch branching enzyme II (SBEII), D1 makes use of an approach using two isoforms of soluble starch synthase. The use of a construct comprising three genes, of which two are the genes soluble starch synthase II and III (SSII and SSIII), is disclosed in D2 on page 10 and in claim 13.
- 2.2 The dependent claims 10 and 24 cannot be seen as adding anything inventive to the not novel subject-matter to the claims they depend on, as they represent only trivial changes.
- 2.3 Concerning claims 12-15, 18-23, and 29 also see 1.3 (above).
As far as examination was possible (see section VIII), it can be concluded that the starch produced by the plants obtained with the help of the method of D1 exhibits similar if not identical features. Therefore no inventive activity can be acknowledged in view of document D1.
Document D3 discloses the use of a soluble starch synthase gene to produce potato plants containing antisense constructs. The starch produced by these plants shows a viscosity onset temperature which is reduced by at least 5-7°C and it also has a reduced endotherm peak temperature compared to controls (see abstract, p. 4, and Table 4). Once a desirable effect has been achieved, the use of different promoters or the combination with other sequences to obtain better results are routine procedures in the field. Moreover, various other combinations were already proposed in the prior art to modify starch characteristics in all possible ways. D1 explicitly refers to the inhibition of several starch synthetases on p. 6, lines 59 ff.
- 2.4 Claim 25 differs from the subject-matter of D1 in that D1 does not disclose the extraction of the starch from the plant. However, starch extraction is a routine procedure and does not involve any inventive activity.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB99/01902

Re Item VII

Certain defects in the international application

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

Re Item VIII

Certain observations on the international application

Objections because of lack of clarity (Article 6 PCT):

1. Claim 1 is not clear because of the following:
 - It is not defined which characteristics are to be modified.
 - The term "...an enzyme having starch synthase activity..." is not supported by the description as it encompasses **any** starch synthase. However, the description only discloses the use of SSII and SSIII.
2. The term "substantially" in claim 2 is unclear as in technical terms something either is simultaneous or it is not.
3. Claim 5 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. Neither the properties which are to be modified nor the kind of modification to be carried out are specified
4. The relative terms used in claims 12-15 and 19-23 to describe technical features of starch have no well-recognised meaning and leave the reader in doubt as to the meaning of the technical features to which they refer, thereby rendering the definition of the subject-matter of said claims unclear (Article 6 PCT).
5. Claim 18 contains a reference to the drawings. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.
6. Claims 20 and 21 seem to be redundant.